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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,144	05/30/2001	Eva Sevick-Muraca	017575.0680	9131

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DALLAS, TX 75201-2980

EXAMINER

LIN, JEYUHU

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/12/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/870,144

Applicant(s)

SEVICK-MURACA ET AL.

Examiner

Jeoyuh Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Priority*

1. If applicant desires priority under 35 U.S.C. 119 (e) and/or 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage

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commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

-Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

-New claims of foreign priorities were made on March 17, 2003, as paper # 5.

2. Applicants appear to be claiming foreign prior benefits under 35 USC 119 (a-d) using prior documents, US 60/039318 and PCT/US98/02354. The claims are objected to because the priority documents claimed are only eligible for claiming 35 USC 119 (e) and 120 benefits, respectively.

### ***Specification***

3. The abstract of the disclosure is objected to because the use of the word, "consists" in line 2 signifies the use legal language. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

-Claims 1-5, 7-14, 16-18, 21-28, and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al. (Pat. # 5,485,530)

Lakowicz et al. teaches a method and apparatus for multi-dimensional phase fluorescence lifetime imaging, comprising the steps of introducing a contrast agent,

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wherein the agent is selected in accordance with a predetermined relationship between degree of image contrast and fluorescence yield (column 5, lines 5-10 and 55-63 and column 10, lines 30-67) or lifetime (column 11, lines 15-25), exposing the tissue to light (column 6, lines 43-55, detecting a light emission from tissue (column 10, lines 53-58), generating an image (column 7, lines 30-50), wherein the fluorescence lifetime is less than 5 ns, toward a range between .2-2ns (column 5, lines 5-10 and column 20, lines 35-40), wherein said generating includes determining a modulation amplitude change and a phase change of light relative to the excitation light (column 12, lines 40-60), wherein the mathematical expression is in a frequency domain form and the image contrast is provided in terms of at least one of phase shift contrast, and evaluating first and second emission (column 6, lines 20-30). While Lakowicz et al. does not teach the contrast agent of having a fluorescent lifetime within a factor of 10 of the mean time of flight, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to select a contrast agent fitting of the said limitation in order to maximize contrast and image clarity.

-Claims 6, 15, 19, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al., as applied to claims 1, 27, 33, and 39 above, and further in view of Sevic-Muraca et al. (Pat. # 5,865,754).

All the claims are considered to be met by Lakowicz et al. except that it does not teach the use of diffusion equation approximation. Sevic-Muraca et al. teaches a fluorescence imaging system and method comprising the use of diffusion coefficient and method. (column 6). It would have been obvious to one having ordinary skill in the art

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at the time the invention was made to adapt the teachings of Sevick-Muraca et al. to the steps as taught by Lakowicz et al. such that the spatial and temporal transport of light in tissue could be further approximated and described.

-Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sevick-Muraca et al., and further in view of Lakowicz et al. (Pat. # 5,865,754)

Sevick-Muraca et al. teaches a method comprising introducing a contrast agent, exposing the tissue to an excitation light (column 1, line 14), detecting light emission (column 4, lines 5-10 and 66 and 67), generating an image of the tissue by mapping spatial variation of fluorescence characteristic of tissue in accordance with mathematical variation (column 4, lines 40-55, column 6, lines 25-57 and claims 6-8), determining the fluorescence yield of the contrast agent, wherein the mathematical expression corresponds to a diffusion equation (column 6) in frequency domain form (column 8), and first and second emission (column 18, line 40). However, it does not teach the selection of a contrast agent based on the obtained data, or a specific value for fluorescence lifetime. Lakowicz et al. teaches both limitations, as stated above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt the teachings of Lakowicz et al. to the steps as taught by Sevick-Muraca et al. such that the molecular and chemical details of the tissue environment could be imaged and enhanced, and that distance-selective could be made.

**Conclusion**

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Zarling et al. ('656) teaches a method for performing the detection of analytes.

-Rao et al. teaches a method and apparatus to perform trans-cutaneous analyte monitoring using fluorescence means.

-Essenpreis et al. ('504) teaches a method for detecting a biological matrix using light.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on Monday-Friday from 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl, can be reached at (703) 308-2262. The fax number for this Group is (703) 308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group receptionist whose telephone number is (703) 308-0858.

JYL  
JYL

August 31, 2003

  
DENNIS RUHL  
PRIMARY EXAMINER